UROGESIC BLUE- methenamine, sodium phosphate, monobasic, methylene blue, and hyoscyamine sulfate tablet, coated
EDWARDS PHARMACEUTICALS, INC.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

UROGESIC-BLUE™

Rx Only

Description

Each tablet contains:

Methenamine, USP	81.6 mg
Monobasic Sodium Phosphate, USP	40.8 mg
Methylene Blue, USP	10.8 mg
Hyoscyamine Sulfate, USP	0.12 mg

Inactive ingredients include: microcrystalline cellulose, NF, mannitol, USP, croscarmellose sodium, NF, magnesium stearate, NF and lake blend blue.

HYOSCYAMINE SULFATE is an alkaloid of belladonna. Exists as a white crystalline powder. Affected by light. It is very soluble in water; freely soluble in alcohol; practically insoluble in ether.

METHENAMINE exists as colorless, lustrous crystals or white crystalline powder. Its solutions are alkaline to litmus. Freely soluble in water; soluble in alcohol and in chloroform.

METHYLENE BLUE exists as dark green crystals. It is soluble in water and in chloroform; sparingly soluble in alcohol.

MONOBASIC SODIUM PHOSPHATE exists as a white crystalline powder. Its solutions are acidic to litmus. It is freely soluble in water and practically insoluble in alcohol.

CLINICAL PHARMACOLOGY

HYOSCYAMINE is a parasympatholytic which relaxes smooth muscles and thus produces an antispasmodic effect. It is well absorbed from the gastrointestinal tract and is rapidly distributed throughout body tissues. Most is excreted in the urine within 12 hours, 13% to 50% being unchanged. Its biotransformation is hepatic. Its protein binding is moderate.

METHENAMINE degrades in an acidic urine environment releasing formaldehyde which provides bactericidal or bacteriostatic action. It is well absorbed from the gastrointestinal tract. 70% to 90% reaches the urine unchanged at which point it is hydrolyzed if the urine is acidic. Within 24 hours it is almost completely (90%) excreted; of this amount at pH 5, approximately 20% is formaldehyde. Protein binding: some formaldehyde is bound to substances in the urine and surrounding tissues. Methenamine is freely distributed to body tissue and fluids but is not clinically significant as it does not hydrolyze at pH greater than 6.8.

METHYLENE BLUE possesses weak antiseptic properties. It is well absorbed in the gastrointestinal tract and is rapidly reduced to leukomethylene blue which is stabilized in some combination form in the urine. 75% is excreted unchanged.

MONOBASIC SODIUM PHOSPHATE helps to maintain an acid pH in the urine necessary for the degradation of methenamine.

INDICATIONS AND USAGE

UROGESIC-BLUE™ is indicated for the treatment of symptoms of irritative voiding. Indicated for the relief of local symptoms, such as hypermotility which accompany lower urinary tract infections and as antispasmodic. Indicated for the relief of urinary tract symptoms caused by diagnostic procedures.

CONTRAINDICATIONS

UROGESIC-BLUE™ is contraindicated in patients with a hypersensitivity to any of the ingredients. Risk-benefit should be considered when the following medical problems exist: Cardiac disease (especially cardiac arrythmias, congestive heart failure, coronary heart disease, mitral stenosis); gastrointestinal tract obstructive disease; glaucoma; myasthenia gravis; acute urinary retention may be precipitated in obstructive uropathy (such as bladder neck obstruction due to prostatic hypertrophy).

WARNINGS

Do not exceed recommended dosage. If rapid pulse, dizziness, or blurring of vision occurs **discontinue use immediately.**

PRECAUTIONS

Cross sensitivity and/or related problems

patients intolerant of belladonna alkaloids may be intolerant of this medication also.

Pregnancy/Reproduction

(Pregnancy Category C)

hyoscyamine and methenamine cross the placenta. Studies have not been done in animals or humans. It is not known whether **UROGESIC-BLUE™** tablets cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. **UROGESIC-BLUE™** tablets should be given to a pregnant woman only if clearly needed.

Breast-feeding

problems in humans have not been documented; however, methenamine and traces of hyoscyamine are excreted in breast milk.

Prolonged use

there have been no studies to establish the safety of prolonged use in humans. No known long-term animal studies have been performed to evaluate carcinogenic potential.

Pediatric

infants and young children are especially susceptible to the toxic effect of the belladonna alkaloids.

Geriatric

use with caution in elderly patients as they may respond to usual doses of hyoscyamine with excitement, agitation, drowsiness, or confusion.

Drug Interactions

because of this product's effect on gastrointestinal motility and gastric emptying, it may decrease the absorption of other oral medications during concurrent use such as: urinary alkalizers; thiazide diuretics

(may cause the urine to become alkaline reducing the effectiveness of methenamine by inhibiting its conversion to formaldehyde); antimuscarinics (concurrent use may intensify antimuscarinic effects of hyoscyamine because of secondary antimuscarinic activities of these medications); antacids/antidiarrheals (may reduce absorption of hyoscyamine, concurrent use with antacids may cause urine to become alkaline reducing effectiveness of methenamine by inhibiting its conversion to formaldehyde) doses of these medications should be spaced 1 hour apart from doses of hyoscyamine; antimyasthenics (concurrent use with hyoscyamine may further reduce intestinal motility); ketoconazole (patients should be advised to take this combination at least 2 hours after ketoconazole); monoamine oxidase (MAO) Inhibitors (concurrent use may intensify antimuscarinic side effects, opoid (narcotic) analgesics may result in increased risk of severe constipation); sulfonamides (these drugs may precipitate with formaldehyde in the urine, increasing the danger of crystalluria).

Patients should be advised that the urine may become blue to blue green and the feces may be discolored as a result of the excretion of methylene blue.

ADVERSE REACTIONS

Cardiovascular – rapid pulse, flushing

Central Nervous System – blurred vision, dizziness

Respiratory – shortness of breath or troubled breathing

Genitourinary – difficulty micturition, acute urinary retention

Gastrointestinal – dry mouth, nausea/vomiting

DRUG ABUSE AND DEPENDENCE

A dependence on the use of **UROGESIC-BLUE™** has not been reported and due to the nature of its ingredients, abuse of **UROGESIC-BLUE™** is not expected.

OVERDOSAGE

Emesis or gastric lavage. Slow intravenous administration of physostigmine in doses of 1 mg to 4 mg (0.5 mg to 1 mg in children), repeated as needed in one to two hours to reverse severe antimuscarinic symptoms. Administration of small doses of diazepam to control excitement and seizures. Artificial respiration with oxygen if needed for respiratory depression. Adequate hydration. Symptomatic treatment as necessary.

DOSAGE AND ADMINISTRATION

Adults

One tablet orally 4 times per day followed by liberal fluid intake.

Older Children

Dosage must be individualized by physician. Not recommended for use in children up to 6 years of age.

HOW SUPPLIED

UROGESIC-BLUE™ are light blue to blue, oval, biconvex tablets debossed with "ED UB" with scoreline on one side and plain on the other side. Supplied in bottles of 30 tablets (NDC 0485-0151-30).

CAUTION

Rx ONLY

STORAGE

Store at 25° C (77° F); excursions permitted to 15° C to 30° C (59° F to 86° F) [See USP Controlled Room Temperature]. Keep container tightly closed.

Manufactured for:
Edwards Pharmaceutical, Inc.
111 W. Mulberry St. Ripley, Mississippi 38663

Manufactured by:
Belcher Pharmaceuticals, LLC.
Largo, FL 33777

November 2014
R-1410

PRINCIPAL DISPLAY PANEL - 30 Tablet Bottle Label

FORMULATION

UROGESIC-BLUE™

URINARY ANTISEPTIC ANTISPASMODIC

DESCRIPTION: Each tablet contains:

Methenamine, USP 81.6 mg

Monobasic Sodium Phosphate, USP 40.8 mg

Methylene Blue, USP 10.8 mg

Hyoscyamine Sulfate, USP 0.12 mg

CONTENTS: 30 TABLETS

Rx ONLY

Manufactured for

EDWARDS PHARMACEUTICAL, INC.

Berwyn, PA

UROGESIC BLUE

methenamine, sodium phosphate, monobasic, methylene blue, and hyoscyamine sulfate tablet, coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0485-0151
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METHENAMINE (UNII: J50OIX95QV) (METHENAMINE - UNII:J50OIX95QV)	METHENAMINE	81.6 mg
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, MONOBASIC	40.8 mg
METHYLENE BLUE (UNII: T42P99266K) (METHYLENE BLUE CATION - UNII:ZMZ79891ZH)	METHYLENE BLUE	10.8 mg
HYOSCYAMINE SULFATE (UNII: F2R8V82B84) (HYOSCYAMINE - UNII:PX44XO846X)	HYOSCYAMINE SULFATE	0.12 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MANNITOL (UNII: 3OWL53L36A)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	blue (LIGHT BLUE)	**Score**	2 pieces
Shape	OVAL	**Size**	13mm

Flavor		**Imprint Code**	ED;UB
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0485-0151-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/19/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/19/2010	

Labeler - EDWARDS PHARMACEUTICALS, INC. (195118880)

Establishment

Name	Address	ID/FEI	Business Operations
Belcher Pharmaceuticals, LLC		965167955	manufacture(0485-0151) , analysis(0485-0151) , pack(0485-0151) , label(0485-0151)

Revised: 8/2019 EDWARDS PHARMACEUTICALS, INC.